

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings of claims in the application.

1. (Currently amended) A method for evaluating a quality of a calibration of an analyte sensor, the method comprising:

receiving a data stream from an analyte sensor, including one or more sensor data points;

receiving reference data from a reference analyte monitor, including one or more reference data points;

providing at least one matched data pair by matching reference analyte data to substantially time corresponding sensor data;

forming a calibration set including said at least one matched data pair;

evaluating a quality of said calibration set using a statistical ~~and/or~~ or clinical association of at least one matched data pair;

converting sensor data into calibrated data; and

controlling a user interface responsive to the quality of said calibration set; ~~wherein the step of controlling a user interface comprises requesting additional reference data on the user interface.~~

2. (Original) The method of claim 1, wherein the step of receiving sensor data comprises receiving a data stream that has been algorithmically smoothed.

3. (Original) The method of claim 1, wherein the step of receiving sensor data comprises algorithmically smoothing said data stream.

4. (Original) The method of claim 1, wherein the step of receiving sensor data comprises receiving sensor data from a substantially continuous glucose sensor.

5. (Original) The method of claim 1, wherein the step of receiving sensor data comprises receiving sensor data from an implantable glucose sensor.

6. (Original) The method of claim 1, wherein the step of receiving sensor data comprises receiving sensor data from a subcutaneously implantable glucose sensor.

7. (Original) The method of claim 1, wherein the step of receiving reference data comprises receiving reference data from a self-monitoring blood glucose test.

8. (Original) The method of claim 1, wherein the step of receiving reference data comprises downloading reference data via a cabled connection.

9. (Original) The method of claim 1, wherein the step of receiving reference data comprises downloading reference data via a wireless connection.

10. (Original) The method of claim 1, wherein the step of receiving reference data from a reference analyte monitor comprises receiving within a receiver internal communication from a reference analyte monitor integral with said receiver.

11. (Canceled)

12. (Previously presented) The method of claim 1, wherein the step of evaluating a quality of said calibration set based on a data association function comprises performing linear least squares regression.

13-16. (Canceled)

17. (Previously presented) The method of claim 1, wherein the step of controlling a user interface includes alerting the user dependent upon a quality of said calibration set.

18. (Previously presented) The method of claim 1, wherein the step of controlling a user interface includes altering the user interface dependent upon a quality of said calibration set.

19. (Previously presented) The method of claim 1, wherein the step of controlling a user interface includes at least one of providing color-coded information, trend information, directional information, gauges, and fail-safe information dependent upon a quality of said calibration set.

20. (Currently amended) A system for evaluating a quality of a calibration of an analyte sensor, the system comprising:

means for receiving a data stream from an analyte sensor, including a plurality of time-spaced sensor data points;

means for receiving reference data from a reference analyte monitor, including one or more reference data points;

means for providing one or more matched data pairs by matching reference analyte data to substantially time corresponding sensor data;

means for forming a calibration set including at least one matched data pair;

means for converting sensor data into calibrated data;

means for evaluating a quality of said calibration set using a statistical ~~and/or~~ or clinical association of at least one matched data pair; and

means for controlling a user interface responsive to the quality of said calibration set, ~~wherein the means for controlling a user interface is configured to request additional reference data on the user interface.~~

21. (Original) The system of claim 20, wherein said means for receiving sensor data comprises means for receiving sensor data that has been algorithmically smoothed.

22. (Original) The system of claim 20, wherein said means for receiving sensor data comprises means for algorithmically smoothing said receiving sensor data.

23. (Original) The system of claim 20, wherein said means for receiving sensor data comprises means for receiving sensor data from substantially continuous glucose sensor.

24. (Original) The system of claim 20, wherein said means for receiving sensor data comprises means for receiving sensor data from an implantable glucose sensor.

25. (Original) The system of claim 20, wherein said means for receiving sensor data comprises means for receiving sensor data from subcutaneously implantable glucose sensor.

26. (Original) The system of claim 20, wherein said means for receiving reference data comprises means for receiving reference data from a self-monitoring blood glucose test.

27. (Original) The system of claim 20, wherein said means for receiving reference data comprises means for downloading reference data via a cabled connection.

28. (Original) The system of claim 20, wherein said means for receiving reference data comprises means for downloading reference data via a wireless connection.

29. (Original) The system of claim 20, wherein said means for receiving reference data from a reference analyte monitor comprises means for receiving within a receiver internal communication from a reference analyte monitor integral with said receiver.

30. (Original) The system of claim 20, wherein said means for evaluating the quality of said calibration set comprises means for performing one of linear regression, non-linear regression, rank correlation, least mean square fit, mean absolute deviation, and mean absolute relative difference.

31. (Original) The system of claim 20, wherein said means for evaluating the quality of said calibration set comprises means for performing linear least squares regression.

32-35. (Canceled)

36. (Previously presented) The system of claim 20, wherein said means for controlling a user interface includes means for alerting the user dependent upon a quality of said calibration.

37. (Previously presented) The system of claim 20, wherein said means for controlling a user interface includes means for altering the user interface dependent upon a quality of said calibration.

38. (Previously presented) The system of claim 20, wherein said means for controlling a user interface includes at least one of providing color-coded information, trend information, directional information, and fail-safe information.

39. (Currently amended) A computer system for evaluating a quality of a calibration of an analyte sensor, the computer system comprising:

a sensor data receiving module that receives a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;

a reference data receiving module that receives reference data from a reference analyte monitor, including one or more reference data points;

a data matching module that forms one or more matched data pairs by matching reference data to substantially time corresponding sensor data;

a calibration set module that forms a calibration set including at least one matched data pair;

a quality evaluation module that evaluates a quality of said calibration set using a statistical ~~and/or~~ or clinical association of at least one matched data pair;

a sensor data transformation module that converts sensor data into calibrated data;

and

an interface control module that controls a display of a user interface responsive to the quality of said calibration set, ~~wherein the interface control module is configured to request additional reference data on the user interface.~~

40. (Original) The computer system of claim 39, wherein said sensor data receiving module receives sensor data that has been algorithmically smoothed.

41. (Original) The computer system of claim 39, further comprising a data smoothing module that algorithmically smoothes sensor data received from said sensor data receiving module.

42. (Original) The computer system of claim 39, wherein said sensor data receiving module is adapted to receive sensor data from substantially continuous glucose sensor.

43. (Original) The computer system of claim 39, wherein said sensor data receiving module is adapted to receive sensor data from an implantable glucose sensor.

44. (Original) The computer system of claim 39, wherein said sensor data receiving module is adapted to receive sensor data from subcutaneously implantable glucose sensor.

45. (Original) The computer system of claim 39, wherein said reference data receiving module is adapted to receive reference data from a self-monitoring blood glucose test.

46. (Original) The computer system of claim 39, wherein said reference data receiving module is adapted to download reference data via a cabled connection.

47. (Original) The computer system of claim 39, wherein said reference data receiving module is adapted to download reference data via a wireless connection.

48. (Original) The computer system of claim 39, wherein said reference data receiving module is adapted to receive reference data from a reference analyte monitor integral with said receiver.

49. (Canceled)

50. (Previously presented) The computer system of claim 39, further comprising a quality evaluation module that evaluates a quality of said calibration set based on a data association function comprising a linear least squares regression.

51-54. (Canceled)

55. (Previously presented) The computer system of claim 39, wherein said interface control module alerts the user based upon a quality of said calibration set.

56. (Previously presented) The computer system of claim 39, wherein said interface control module alters the user interface based upon a quality of said calibration set.

57. (Previously presented) The computer system of claim 39, wherein said interface control module provides at least one of color-coded information, trend information, directional information, and fail-safe information.

58. (Canceled)

59. (Currently amended) A method for evaluating a quality of a calibration of an analyte sensor, the method comprising:

receiving analyte sensor data from an analyte sensor;

receiving reference data from a reference analyte monitor;

providing a calibration set comprising at least one matched data pair by matching reference analyte data to substantially time corresponding sensor data;

evaluating a quality of said calibration set based on a statistical ~~and/or~~ or clinical association of at least one matched data pair;

modifying the calibration set by removing ~~and/or~~ or displacing one or more matched data pairs to form a new calibration set; and

converting the sensor data into calibrated data responsive to the quality of the modified calibration set meeting a criterion.

60. (Canceled)

61. (Currently amended) A computer system for evaluating a quality of a calibration of an analyte sensor, the computer system comprising:

a sensor data module configured to receive analyte sensor data from a substantially continuous analyte sensor;

a reference input module configured to receive reference data from a reference analyte monitor;

a processor module configured to form a calibration set comprising at least one matched data pair;

a quality evaluation module configured to evaluate a quality of said calibration set based on a statistical ~~and/or~~ or clinical association of at least one matched data pair, wherein the processor module is configured to modify the calibration set by removing ~~and/or~~ or displacing one or more matched data pairs to form a new calibration set, and wherein the processor module is configured to convert the sensor data into calibrated sensor data responsive to the quality of the modified calibration set meeting a criterion.

62. (Currently amended) A method for evaluating a quality of a calibration of a glucose sensor, the method comprising:

receiving sensor data from a glucose sensor, including one or more sensor data points;

receiving reference data from a reference glucose monitor, including one or more reference data points;

providing one or more matched data pairs by matching reference glucose data to substantially time corresponding sensor glucose data;

forming a calibration set including at least one matched data pair;

evaluating a quality of said calibration set based on a statistical ~~and/or~~ or a clinical association of at least one matched data pair;

modifying the calibration set by removing a most discordant ~~and/or~~ or oldest matched data pair responsive to the quality of said calibration set not meeting one or more criteria; and

processing real-time sensor data responsive to the quality of said modified calibration set meeting a criterion.

63-72. (Canceled)

73. (Previously presented) The method of claim 59, wherein the step of evaluating a quality comprises evaluating the quality using a statistical analysis.

74. (Previously presented) The method of claim 59, wherein the step of evaluating a quality comprises evaluating the quality using a clinical acceptability analysis.

75. (Previously presented) The method of claim 59, further comprising calibrating the sensor data, wherein the step of calibrating is performed during initialization of the analyte sensor.

76. (Previously presented) The method of claim 59, further comprising calibrating the sensor data, wherein the step of calibrating is performed after initialization of the analyte sensor.

77. (Previously presented) The method of claim 59, further comprising calibrating the sensor data, wherein the step of calibrating is performed using a single matched data pair.

78. (Previously presented) The method of claim 59, further comprising calibrating the sensor data, wherein the step of calibrating is performed using more than one matched data pairs.

79. (Previously presented) The method of claim 59, wherein the step of receiving sensor data comprises receiving sensor data that has been algorithmically smoothed.

80. (Previously presented) The method of claim 59, wherein the step of receiving sensor data comprises algorithmically smoothing said sensor data.

81. (Previously presented) The method of claim 59, wherein the step of receiving sensor data comprises receiving sensor data from a substantially continuous glucose sensor.

82. (Previously presented) The method of claim 59, further comprising displaying a graphical representation of calibrated sensor data.

83-92. (Canceled)

93. (Previously presented) The system of claim 61, wherein the processor module is configured to calibrate sensor data during initialization of the analyte sensor.

94. (Previously presented) The system of claim 61, wherein the processor module is configured to calibrate sensor data after initialization of the analyte sensor.

95. (Previously presented) The system of claim 61, wherein the processor module is configured to calibrate sensor data using a single matched data pair.

96. (Previously presented) The system of claim 61, wherein the processor module is configured to calibrate sensor data using more than one matched data pairs.

97. (Previously presented) The system of claim 61, wherein said sensor data module receives sensor data that has been algorithmically smoothed.

98. (Previously presented) The system of claim 61, further comprising a data smoothing module that algorithmically smoothes sensor data received from said sensor data module.

99. (Previously presented) The system of claim 61, wherein said sensor data receiving module is adapted to receive sensor data from a substantially continuous glucose sensor.

100. (Previously presented) The system of claim 61, further comprising an output module configured to display calibrated sensor data.

101. (Previously presented) The system of claim 61, wherein the quality evaluation module is configured to evaluate the quality using a statistical analysis.

102. (Previously presented) The system of claim 61, wherein the quality evaluation module is configured to evaluate the quality using a clinical acceptability analysis.

103. (Previously presented) The method of claim 62, further comprising calibrating sensor data, wherein the step of calibrating is performed during initialization of the glucose sensor.

104. (Previously presented) The method of claim 62, further comprising calibrating sensor data, wherein the step of calibrating is performed after initialization of the analyte sensor.

105. (Previously presented) The method of claim 62, further comprising calibrating the sensor data, wherein the step of calibrating is performed using a single matched data pair.

106. (Previously presented) The method of claim 62, further comprising calibrating sensor data, wherein the step of calibrating is performed using more than one matched data pairs.

107. (Previously presented) The method of claim 62, wherein the step of receiving sensor data comprises receiving sensor data that has been algorithmically smoothed.

108. (Previously presented) The method of claim 62, wherein the step of receiving sensor data comprises algorithmically smoothing said sensor data.

109. (Previously presented) The method of claim 62, wherein the step of receiving sensor data comprises receiving sensor data from a substantially continuous glucose sensor.

110. (Previously presented) The method of claim 62, further comprising calibrating sensor data and displaying a graphical representation of the calibrated sensor data.

111. (Previously presented) The method of claim 1, wherein the step of evaluating a quality uses a statistical analysis.

112. (Previously presented) The method of claim 111, wherein the statistical analysis comprises a cost function.

113. (Previously presented) The method of claim 112, wherein the cost function is selected from the group consisting of linear regression, non-linear mapping/regression, rank correlation, least mean square fit, mean absolute deviation, and mean absolute relative difference.

114. (Previously presented) The method of claim 1, wherein the step of evaluating a quality uses a clinical acceptability analysis.

115. (Previously presented) The method of claim 1, wherein the step of evaluating a quality uses a statistical analysis and a clinical analysis.

116. (Previously presented) The method of claim 1, wherein the step of controlling a user interface comprises altering the user interface when the quality meets a criterion.

117. (Previously presented) The method of claim 1, wherein the step of controlling a user interface comprises displaying error bars and/or a range of values when the quality meets a criterion.

118. (Previously presented) The method of claim 1, wherein the step of controlling a user interface comprises displaying calibrated sensor data on the user interface, and wherein the step of controlling a user interface further comprises discontinuing display of calibrated data when the quality meets a criterion.

119. (Previously presented) The method of claim 1, wherein the step of controlling a user interface comprises displaying calibrated sensor data on the user interface, and wherein the step of controlling a user interface further comprises modifying a format, resolution and/or content of data on the user interface when the quality meets a criterion.

120. (Previously presented) The system of claim 20, wherein said means for evaluating a quality uses a statistical analysis.

121. (Previously presented) The system of claim 120, wherein the statistical analysis comprises a cost function.

122. (Previously presented) The system of claim 20, wherein said means for evaluating a quality uses a clinical acceptability analysis.

123. (Previously presented) The system of claim 20, wherein said means for evaluating a quality uses a statistical analysis and a clinical analysis.

124. (Previously presented) The system of claim 20, wherein said means for controlling a user interface comprises altering the user interface when the quality meets a criterion.

125. (Previously presented) The system of claim 20, wherein said means for controlling a user interface comprises displaying error bars and/or a range of values when the quality meets a criterion.

126. (Previously presented) The system of claim 20, wherein said means for controlling a user interface comprises means for displaying calibrated sensor data on the user interface, and wherein said means for controlling a user interface further comprises discontinuing display of calibrated data when the quality meets a criterion.

127. (Previously presented) The system of claim 20, wherein said means for controlling a user interface comprises means for displaying calibrated sensor data on the user interface, and wherein said means for controlling a user interface further comprises modifying a format, resolution and/or content of data on the user interface when the quality meets a criterion.

128. (Previously presented) The system of claim 39, wherein said quality evaluation module uses a statistical analysis.

129. (Previously presented) The system of claim 128, wherein the statistical analysis comprises a cost function.

130. (Previously presented) The system of claim 129, wherein the cost function is selected from the group consisting of linear regression, non-linear mapping/regression, rank correlation, least mean square fit, mean absolute deviation, and mean absolute relative difference.

131. (Previously presented) The system of claim 39, wherein said quality evaluation module uses a clinical acceptability analysis.

132. (Previously presented) The system of claim 39, wherein said quality evaluation module uses a statistical analysis and a clinical analysis.

133. (Previously presented) The system of claim 39, wherein said interface control module alters the user interface when the quality meets a criterion.

134. (Previously presented) The system of claim 39, wherein said interface control module displays error bars and/or a range of values when the quality meets a criterion.

135. (Previously presented) The system of claim 39, wherein said interface control module displays calibrated sensor data on the user interface, and wherein said interface control module further discontinues display of calibrated data when the quality meets a criterion.

136. (Previously presented) The system of claim 39, wherein said interface control module displays calibrated sensor data on the user interface, and wherein said interface control module further modifies a format, resolution and/or content of data on the user interface when the quality meets a criterion.

137-144. (Canceled)

145. (Previously presented) The method of claim 62, wherein the step of evaluating a quality uses a statistical analysis.

146. (Previously presented) The method of claim 145, wherein the statistical analysis comprises a cost function.

147. (Previously presented) The method of claim 146, wherein the cost function is selected from the group consisting of linear regression, non-linear mapping/regression, rank correlation, least mean square fit, mean absolute deviation, and mean absolute relative difference.

148. (Previously presented) The method of claim 62, wherein the step of evaluating a quality uses a clinical acceptability analysis.

149. (Previously presented) The method of claim 62, wherein the step of evaluating a quality uses a statistical analysis and a clinical analysis.

150. (Previously presented) The method of claim 62, wherein the step of processing real time sensor data comprises converting sensor data into calibrated sensor data.

151. (Previously presented) The method of claim 62, wherein the step of processing real time sensor data comprises modifying a method of calibrating the sensor data.

152. (Previously presented) The method of claim 62, wherein the step of processing real time sensor data comprises modifying the calibration set.

153. (Previously presented) The method of claim 62, wherein the step of processing real time sensor data comprises.

154. (Previously presented) The method of claim 1, further comprising a step of forming a modified calibration set comprising the received reference data.

155. (Currently amended) The method of claim 154, ~~wherein the further comprising a~~ step of converting sensor data into calibrated data ~~uses~~ using the modified calibration set.

156. (Previously presented) The method of claim 1, wherein the calibration set comprises at least two matched data pairs.

157. (Previously presented) The system of claim 20, further comprising a means of forming a modified calibration set comprising the received reference data.

158. (Previously presented) The system of claim 157, wherein the means of converting sensor data into said calibrated data is configured to use the modified calibration set.

159. (Previously presented) The system of claim 20, wherein the calibration set comprises at least two matched data pairs.

160. (Previously presented) The computer system of claim 39, further comprising a calibration set modifier module configured to form a modified calibration set comprising the received reference data.

161. (Previously presented) The computer system of claim 161, wherein the sensor data transformation module is configured to use the modified calibration set.

162. (Previously presented) The computer system of claim 39, wherein the calibration set comprises at least two matched data pairs.

163. (Previously presented) The method of claim 59, further comprising calculating a conversion function using the modified calibration set.

164. (Previously presented) The method of claim 59, wherein the calibration set comprises at least two matched data pairs.

165. (Previously presented) The method of claim 59, wherein the step of modifying the calibration set comprises removing a most discordant and/or oldest matched data pair responsive to the quality of said calibration set not meeting one or more criteria.

166. (Previously presented) The computer system of claim 61, wherein the quality evaluation module calculates a conversion function using the modified calibration set.

167. (Previously presented) The computer system of claim 61, wherein the calibration set comprises at least two matched data pairs.

168. (Previously presented) The computer system of claim 61, wherein the processor module is configured to remove a most discordant and/or oldest matched data pair responsive to the quality of said calibration set not meeting one or more criteria.

169. (Previously presented) The method of claim 62, further comprising calculating a conversion function using the modified calibration set.

170. (Previously presented) The method of claim 62, wherein the calibration set comprises at least two matched data pairs.

171. (New) A method for evaluating a quality of a calibration of an analyte sensor, the method comprising:

- receiving a data stream from an analyte sensor, including one or more sensor data points;

- receiving reference data from a reference analyte monitor, including one or more reference data points;

- providing at least one matched data pair by matching reference analyte data to substantially time corresponding sensor data;

- forming a calibration set including said at least one matched data pair;

- evaluating a quality of said calibration set using a statistical or clinical association of at least one matched data pair with one or more clinically-based or physiologically-based criteria;

- converting sensor data into calibrated data; and

- controlling a user interface responsive to the quality of said calibration set.

172. (New) A system for evaluating a quality of a calibration of an analyte sensor, the system comprising:

means for receiving a data stream from an analyte sensor, including a plurality of time-spaced sensor data points;

means for receiving reference data from a reference analyte monitor, including one or more reference data points;

means for providing one or more matched data pairs by matching reference analyte data to substantially time corresponding sensor data;

means for forming a calibration set including at least one matched data pair;

means for converting sensor data into calibrated data;

means for evaluating a quality of said calibration set using a statistical or clinical association of at least one matched data pair with one or more clinically-based or physiologically-based criteria; and

means for controlling a user interface responsive to the quality of said calibration set.

173. (New) A computer system for evaluating a quality of a calibration of an analyte sensor, the computer system comprising:

a sensor data receiving module that receives a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;

a reference data receiving module that receives reference data from a reference analyte monitor, including one or more reference data points;

a data matching module that forms one or more matched data pairs by matching reference data to substantially time corresponding sensor data;

a calibration set module that forms a calibration set including at least one matched data pair;

a quality evaluation module that evaluates a quality of said calibration set using a statistical or clinical association of at least one matched data pair with one or more clinically-based or physiologically-based criteria;

a sensor data transformation module that converts sensor data into calibrated data;
and

an interface control module that controls a display of a user interface responsive to the quality of said calibration set.

174. (New) A method for evaluating a quality of a calibration of an analyte sensor, the method comprising:

- receiving analyte sensor data from an analyte sensor;
- receiving reference data from a reference analyte monitor;
- providing a calibration set comprising at least one matched data pair by matching reference analyte data to substantially time corresponding sensor data;
- evaluating a quality of said calibration set based on a statistical or clinical association of at least one matched data pair;
- modifying the calibration set by removing or displacing one or more matched data pairs to form a new calibration set; and
- converting the sensor data into calibrated data responsive to the quality of the modified calibration set meeting one or more clinically-based or physiologically-based criteria.

175. (New) A computer system for evaluating a quality of a calibration of an analyte sensor, the computer system comprising:

- a sensor data module configured to receive analyte sensor data from a substantially continuous analyte sensor;
- a reference input module configured to receive reference data from a reference analyte monitor;
- a processor module configured to form a calibration set comprising at least one matched data pair;
- a quality evaluation module configured to evaluate a quality of said calibration set based on a statistical or clinical association of at least one matched data pair, wherein the processor module is configured to modify the calibration set by removing or displacing one or more matched data pairs to form a new calibration set, and wherein the processor module is configured to convert the sensor data into calibrated sensor data responsive to the quality of the modified calibration set meeting one or more clinically-based or physiologically-based criteria.

176. (New) A method for evaluating a quality of a calibration of a glucose sensor, the method comprising:

receiving sensor data from a glucose sensor, including one or more sensor data points;

receiving reference data from a reference glucose monitor, including one or more reference data points;

providing one or more matched data pairs by matching reference glucose data to substantially time corresponding sensor glucose data;

forming a calibration set including at least one matched data pair;

evaluating a quality of said calibration set based on a statistical or a clinical association of at least one matched data pair;

modifying the calibration set by removing a most discordant or oldest matched data pair responsive to the quality of said calibration set not meeting one or more clinically-based or physiologically-based criteria; and

processing real-time sensor data responsive to the quality of said modified calibration set meeting one or more clinically-based or physiologically-based criteria.